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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/734,836	12/12/2000	Tianci Luo	4-30922A/SYS	4435

1095 7590 01/28/2003

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EXAMINER

WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 01/28/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/734,836

Applicant(s)

LUO ET AL.

Examiner

Ulrike Winkler, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on November 13, 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-80 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Applicant's election with traverse of V in Paper No. 11 is acknowledged. Upon review and reconsideration the following new Election/Restriction requirement is made.

#### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, 14, 20-22, drawn to a bovine immunodeficiency virus vector (BIV) encoding ***gag*** and ***pol*** and encoding a transgene [combination vector], classified in class 424, subclass 187.1.
- II. Claims 23-26, drawn to a bovine immunodeficiency virus vector (BIV) [packaging construct] encoding ***gag*** or ***pol***, contains no transgene, classified in class 424, subclass 187.1.
- III. Claims 55-62, drawn to a bovine immunodeficiency virus vector (BIV) [packaging construct] encoding ***gag*** and ***pol***, classified in class 424, subclass 187.1.
- IV. Claims 8-13, 15-19, 40-54 drawn to a bovine immunodeficiency virus vector (BIV) encoding a transgene [minimal vector construct], classified in class 424, subclass 207.1.
- V. Claims 63-65, drawn to a viral surface protein expression construct [viral surface protein construct], classified in class 424, subclass 224.1.
- VI. Claims 27-30 drawn to a three-plasmid vector transfections method for producing virion particles, classified in class 435, subclass 465.

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- VII. Claims 31, 32, 79 drawn to a method of transferring a gene of interest into a mammalian cell *in vitro* using a vector particle, classified in class 435, subclass 455.
- VIII. Claims 31, 33, 79 drawn to a method of transferring a gene of interest into a mammalian cell *in vivo* using a vector particle, classified in class 800, subclass 23.
- IX. Claims 34-36, drawn a two-plasmid vector transfections method for producing virion particles, classified in class 435, subclass 465.
- X. Claims 37-39 drawn to a method of transferring a gene of interest into a mammalian cell using a vector particle, classified in class 935, subclass 57.
- XI. Claims 78 drawn to a method of transferring a gene to a mammalian cell by administering the a vector, classified in class 435, subclass 320.1.
- XII. Claims 66-72 drawn to a packaging cell/producer cell, classified in class 435, subclass 459.
- XIII. Claims 74-77 drawn to a method of making a packaging cell/producer cell, classified in class 435, subclass 459.
- XIV. Claims 73 and 80 drawn to a virion particle, classified in class 435, subclass 459.

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For the invention of group I above, restriction to one of the following is also required under 35 USC 121. Therefore, if applicant elects the invention of group I, election is further required for one of inventions (A)-(D).

- |      |                          |   |              |
|------|--------------------------|---|--------------|
| (A). | LTR                      | - | (claim 3)    |
| (B). | Tat + Rev                | - | (claims 4,5) |
| (C). | Rev                      | - | (claim 6)    |
| (D). | 2 <sup>nd</sup> promoter | - | (claim 7)    |

For the invention of group II above, restriction to one of the following is also required under 35 USC 121. Therefore, if applicant elects the invention of group II, election is further required for one of inventions (E)-(F).

- |      |                               |   |                 |
|------|-------------------------------|---|-----------------|
| (E). | intron                        | - | (claims 25, 26) |
| (F). | internal ribosomal entry site | - | (claim 24).     |

For each invention of groups IV above, restriction to one of the following is also required under 35 USC 121. Therefore, if applicant elects one of the inventions of group II, election is further required for one of inventions (H)-(O).

- |      |  |   |                 |
|------|--|---|-----------------|
| (H). | BIV packaging signal                     | - | (claim 9)       |
| (I). | 1 <sup>st</sup> promoter LTR             | - | (claims 10, 19) |
| (J). | 1 <sup>st</sup> promoter CMV             | - | (claim 11)      |
| (K). | 2 <sup>nd</sup> promoter CMV, PKG or MND | - | (claim 12)      |
| (L). | RRE                                      | - | (claims 15, 18) |
| (M). | scaffold attachment region               | - | (claim 16)      |
| (N). | central polypurine tract                 | - | (claim 17)      |
| (O). | BIV DNA                                  | - | (claims 40-54)  |

The inventions are distinct, each from the other because of the following reasons:

Inventions (A)-(D) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

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functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for hybridization, expression or activity, the different sequences have different effects.

Inventions (E)-(F) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for hybridization, expression or activity, the different sequences have different effects.

Inventions (H)-(O) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for hybridization, expression or activity, the different sequences have different effects.

Claims 1 and 2 link(s) inventions A-D. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 and 2. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s)

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are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 23 link(s) inventions E-F. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 and 2. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 8 link(s) inventions H-O. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 8. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn

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and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions III-V are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, inventions III-V have separate utility each plasmid produces different proteins, which can be used as an immunogen. The subcombination can also be used to transfer a gene of interest to a cell without the requirement of having made a particle (see claim 78) See MPEP § 806.05(d).

Inventions VI and III-V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does necessarily rely solely on either subcombination as claimed for patentability as evidenced by all subcombination being within the combination, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because each plasmid encodes a different antigen. The subcombination has separate utility such as it expresses



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different proteins which have different antigenic properties. The subcombination can also be used to transfer a gene of interest to a cell without the requirement of having made a particle (see claim 78)

Inventions I and V are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, inventions I and V have separate utility each plasmid produces different proteins which can be used as an immunogen. See MPEP § 806.05(d).

Inventions IX and I, V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does necessarily rely solely on either subcombination as claimed for patentability as evidenced by all subcombination being within the combination, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because each plasmid encodes a different antigen. The subcombination has separate utility such as it expresses different proteins that have different antigenic properties.

Groups XII and XIV are drawn to compositions and they are distinct from Groups VII, VIII, X, XI and XIII are drawn to methods and each is distinct from the other because they utilize different starting materials, therefore the outcomes are not be expected to be the same. Group XII is drawn to a packaging/producer cell, according to the specification, a producer cell line refers to a cell line which is capable of producing recombinant BIV particles. The producer

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cell line should include an integrated BIV construct. A producer cell line is a different composition from a cell that has been transfected with 2 or 3 plasmids, which are not integrated. Group XIV is drawn to a viral particle.

Group VII is drawn to a method for inserting a gene into a cell *in vitro*, the cell is not part a whole organism. Group VIII is drawn to a method of inserting a gene into a cell *in vivo*, here a whole organism is treated with the viral particle. Group X is drawn to a method of inserting a gene into a cell. The virion particles between groups VII, VIII and X are not made by the same methods indicating that the starting materials are not the same. Group XI is drawn to a method of transferring a gene into a mammalian cell by administering a plasmid vector. Group XIII is drawn to a method of making a packing/producer cell utilizing vectors. Though there may be overlap between these methods in question for groups VII, VIII, X, XI and XIII, each utilizes different materials and therefore the outcome is expected to be different.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Applicant is advised that a rejoinder of claims is possible at a later date if the product is eventually found patentable. Guidance on treatment of product and process claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b) is set forth in the Commissioner's Notice of February 28, 1996 published on March 26, 1996 at 1184 O.G. 86.


To facilitate examination under § 103, where product and process claims are presented in the same application, applicant may be called upon under 35 U.S.C. § 121 to elect claims to either the product or process. The claims to the non-elected invention will be withdrawn from further consideration. However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined. In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Ulrike Winkler, Ph.D. 1/27/03